Exhibit K

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

[UNDER SEAL],	:	
Plaintiffs,	:	Case No. _____
	:	FILED IN CAMERA & UNDER SEAL
v.		PURSUANT TO 31 U.S.C. §3730(b)(2)
	:	
[UNDER SEAL],		CIVIL ACTION
	:	
Defendants.		JURY TRIAL DEMANDED
	:	
		DO NOT ENTER INTO PACER
		DO NOT PLACE IN PRESS BOX

COMPLAINT FILED UNDER SEAL

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA;THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WASHINGTON, WISCONSIN, THE DISTRICT OF COLUMBIA, THE CITIES OF CHICAGO AND NEW YORK, *ex rel.*,	:	Case No. _____
JOHN DOE I AND JOHN DOE II,	:	FILED IN CAMERA & UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)
Relators,	:	CIVIL ACTION
v.	:	JURY TRIAL DEMANDED
BOSTON SCIENTIFIC CORPORATION, MEDTRONIC, INC., ST. JUDE MEDICAL, INC., AND BIOTRONIK, INC.	:	DO NOT ENTER INTO PACER DO NOT PLACE IN PRESS BOX
Defendants.	:	

1. Plaintiffs-Relators, John Doe I ("Relator I") and John Doe II ("Relator II")(collectively referred to as "Relators"), by their undersigned attorneys, on behalf of the United States of America ("United States"), and Commonwealths of Massachusetts and Virginia, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Minnesota, Michigan, Montana, Nevada, New Hampshire,

New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Wisconsin, the District of Columbia, the Cities of Chicago and New York (collectively, "the States and Cities") bring this Complaint for damages under the Federal False Claims Act and corresponding state and city False Claims Acts against Defendants Boston Scientific Corporation, Medtronic, Inc., St. Jude Medical, Inc. and Biotronik, Inc. and allege, upon information and belief, as follows:

PRELIMINARY STATEMENT

2. This case is brought pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. § 3279 *et seq.* (the "FCA"), the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and the Stark Law, 42 U.S.C. § 1395nn *et seq.* and pursuant to analogous provisions of state and local law.

3. **This case arises from a nationwide, fraudulent scheme by the largest, and most profitable, medical device manufacturers in the world – Boston Scientific, Medtronic, St. Jude, Biotronik - to cause doctors to overbill for certain services reimbursed by federal and state healthcare programs that were rendered in connection with the required monitoring of patients with implantable pacemakers/defibrillators, known as Cardiac Implantable Electronic Devices ("CIEDs"), causing the submission of false claims**. As set forth more fully below, for several decades through the present, Defendants systematically engaged in a kickback scheme to provide doctors with free technical services in connection with the necessary health monitoring of cardiac patients with CIEDs in exchange for their commitment to recommend use of their products and continued business. Only recently have some Defendants made shoddy attempts to camouflage and attenuate their practices, which remain ongoing. Unfortunately, these subsequent remedial measures are not only insufficient,

but have been done in an effort to disguise the years of fraud committed and still being committed by Defendants.

4. Defendants also systematically paid and continue to pay doctors exorbitant speaker and consulting fees, subsidize fellowship grants at "high volume" institutions, and provide research stipends for, many times, what is considered to be, sham research. These payments to doctors are kickbacks to induce them to use their respective products.

5. The Defendants' deep and pervasive financial inducements taint patient referrals based on their financial incentives and the on-going financial relationship between the manufacturers and the cardiologists, cardiology groups and/or hospitals. Defendants' inducements also run the risk of impacting doctors' judgment as to obtaining the best cardiac product for a patient's particular malady.

6. Defendants continue to knowingly and willingly participate in this fraudulent scheme and collusion-type behavior to prevent their loss of market share. Any manufacturer who runs afoul and fails to participate in this unescapable fraud will run the risk of losing a high volume of business since the majority of products are technically equivalent.

7. Through this fraudulent scheme, Defendants knowingly caused the submission of thousands of false claims for payment to federal and state health care programs, including Medicare, Medicaid, TRICARE, and the Veterans Administration health care program. Accordingly, Defendants are liable under the FCA and respective state FCAs for treble damages and penalties for the claims for reimbursement for the technical component of monitoring patients implanted with their product This action arises under, *inter alia*, the United States Civil False Claims Act, 31 U.S.C. § 3729 *et seq*.

JURISDICTION AND VENUE

8. The Court has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331, and has personal jurisdiction over the Defendants because the Defendants does business in this District.

9. Venue lies under 28 U.S.C. § 1391(b), (c) and 31 U.S.C. § 3732(a) because Defendants operate and transact business within this district and seminal events forming the basis of this Complaint occurred in this district.

PARTIES

10. The real party in interest to the claims set forth herein is the United States of America.

11. Relator I is a resident of the State of New Jersey and a citizen of the United States. Relator I is a board certified and experienced cardiologist.

12. Relator II is a resident of the State of New Jersey and a citizen of the United States. Relator II is a board certified and experienced cardiologist.

13. As further discussed in paragraphs below, Relators are each an original source of the information upon which this Complaint is based, as that phrase is used in the FCA and other laws at issue herein.

14. Relators have direct and independent knowledge on which the allegations herein are based and have voluntarily provided this information to the United States prior to filing this action. Relators have personally observed Defendants' practices and have been privy to meetings, conversations, and other communications. In the regular course of their clinical cardiology practice, the Relators have gained knowledge regarding the workings of the Defendants.

15. Relators have provided / are providing to the United States Attorney and States' Attorneys' General a full disclosure of substantially all material facts supporting this Complaint, as required by the FCA, 31 § 3730(b)(2), and relevant state statutes.

16. Defendant Boston Scientific Corporation ("Boston Scientific") is a Delaware corporation with its principal place of business at 300 Boston Scientific Way, Marlborough, MA 01752-1234.

17. Defendant Medtronic, Inc. ("Medtronic") is a Minnesota corporation with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota.

18. St. Jude Medical, Inc. ("St. Jude") is a Minnesota corporation with a principal place of business at One St. Jude Medical Drive, St. Paul, MN 55117. St. Jude operates its cardiac medical device unit through its St. Jude Cardiovascular Division.

19. Defendant Biotronik, Inc. ("Biotronik") is, upon information and belief, an Oregon Corporation with a principal place of business located at 6024 Jean Rd., Lake Oswego, OR 97035.

20. The Defendants are the four leading cardiac device manufacturers in the United States and all participate in the fraudulent scheme detailed herein.

FACTUAL ALLEGATIONS

I. The Anti-Kickback Statute and the False Claims Act

21. The FCA establishes liability to the United States for an individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," § 3729(a)(l)(A); or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," § 3729(a)(l)(B).[1] "Knowingly" is

[1] In May 2009, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to

defined to include actual knowledge, reckless disregard and deliberate indifference. § 3729(b)(l). No proof of specific intent to defraud is required. *Id.*

22. The AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing ... or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Providing free services that are later reimbursed by federal and state health care programs, as well as providing other payments to doctors to induce them to recommend their respective company's products that are reimbursed by federal and state health care programs are examples of such illegal remuneration. Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7).

23. The AKS arose out of congressional concern that remuneration given to those who can influence health care decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the Medicare and Medicaid programs, among other federal health care programs, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that

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Defendants' conduct for the entire time period alleged in the Complaint by virtue of Section 4(f) of FERA. Section 3279(a)(1)(A), formerly Section 3729(a)(1), of the FCA prior to FERA, and as amended in 1986, applies to conduct on or after May 20, 2009. Section 3729 of the pre-FERA FCA provides, in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval . . .
> * * *
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Publ. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Publ. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

24. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]."

25. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S 10854.

26. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under the federal health care programs.

27. By providing kickbacks to physicians to induce them to prescribe certain Defendant CIEDs, Defendants have caused false claims to be submitted to federal health care programs.

28. Similar requirements and penalties exist under the named State FCA's when illegal kickbacks cause false claims to be submitted to state health care programs.

29. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the FCA civil penalties are $5,500 to $11,000 for violations, such as those alleged here, occurring on or after September 29, 1999.

II. The Stark Law - The Medicare/Medicaid Self-Referral Statute

30. The Physician Self-Referral Statute, 42 U.S.C. § 1395nn *et seq.*, known as the "Stark" law, prohibits the referral of Medicare and Medicaid beneficiaries by a physician to an entity for the provision of "designated health services" if the physician, or the physician's immediate family member, has a financial relationship with the entity, unless a statutory exception applies to that financial relationship.

31. The Stark law may be triggered when (i) a physician, who has a financial relationship with a medical device company, (ii) recommends inpatient and outpatient hospital services (which is considered a "designated health service" under Stark) that (iii) is paid for by a federally funded program (*e.g.,* Medicare). The Stark law prohibits an entity (i.e. Defendants) from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payor) for those referred services.

32. As described more fully below, Defendants, through paid consulting fees, paid fellowships, and other financial arrangements, made payments to physicians in positions to recommend, endorse or use their products, which were reimbursed by federally funded health care programs, resulting in violations of the Stark law.

33. Upon information and belief, the consulting services paid for by Defendants far exceeded those that are reasonable and necessary for the purported legitimate business purposes of said arrangements. The payments made by Defendants far surpassed fair market value for those services rendered.

34. The physician paid personal service "arrangements," described more fully below do not fall within a Stark law exception.

35. These paid financial relationships created by Defendants disguised as consulting fees, research stipends and fellowships, created serious conflicts of interests for physicians who, because of these payments, became "loyal" to certain companies.

III. The Federal Health Care Programs

36. At issue in this case is reimbursement for the "technical component" of monitoring patients with CIEDs. Almost always, monitoring of cardiac patients after a CIED has been implanted is performed by a non-invasive cardiologist or Electrophysiologist. The doctor then submits the claim for payment to the federal health care program(s) for reimbursement.

37. ***Medicare***. Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. See 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program"). Medicare Part A pays for, among other things, the cost of inpatient hospital care. Medicare Part B covers medically necessary services and supplies needed for the diagnosis or treatment of your health condition. This includes outpatient services received at a hospital, doctor's office, clinic, or other health facility. Together, Medicare Part A and Part B are known as Original Medicare.

38. Medicare enters into provider agreements with physicians and hospitals to establish their eligibility to participate in the program. To be eligible for payment under the program physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws.

39. On the Medicare provider enrollment agreement, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> *****
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

CMS Form 855I.

40. Medicare Enrollment Application forms also warn of the penalties involved for falsifying information on the application form, including penalties enumerated under 18 U.S.C. § 1001, § 1128B(a)(1) of the Social Security Act, the Civil False Claims Act, 31 U.S.C. § 3729, § 1128A(a)(1) of the Social Security Act, 18 U.S.C. § 1035, and 18 U.S.C. 1347.

41. In addition, when medical devices are reimbursed under Medicare, sponsors must certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, the Anti-Kickback Statute.

42. ***Medicaid.*** Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50 percent and is as high as 83 percent.

43. The Medicaid programs of all states reimburse for medical devices used during covered medical procedures. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

44. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes.

45. Certifications that physicians supply to the States for Medicaid reimbursement include compliance with the Anti-Kickback Statute, among other federal health care laws.

46. A provider who participates in the Medicaid program must sign an agreement with his or her state that certifies compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

47. ***TRICARE***. TRICARE, administered by the Department of Defense ("DOD"), is the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, arid offer health care to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. TRICARE operates through various military-operated hospitals and clinics worldwide and is supplemented through contracts with civilian health care providers. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

48. TRICARE requires physicians to certify to compliance with the Anti-Kickback Statute, among other federal health care laws.

49. ***Veterans Administration Health Care.*** The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all medically prescribed prosthetic and sensory aids, medical devices, assistive aids, repairs and services are made eligible to Veterans to maximize their independence and enhance their quality of life. Although the term "prosthetic device" may suggest images of artificial limbs, it actually refers to any device that supports or replaces loss of a body part or function and includes a full range of equipment and services for Veterans. This includes but is not limited to, cardiac devices. The system serves approximately four million veterans.

IV. Defendants Were Well Aware that Their Actions Would Cause Doctors to Submit False Claims in Violation of the Anti-Kickback Statute and the False Claims Act

50. Defendants recognized the need to comply with the AKS in promoting their CIEDs to health care professionals. Defendant Medtronic, Inc. was previously under a Corporate Integrity Agreement ("CIA") effective in July 2006 with the Office of Inspector General ("OIG") of the Department of Health and Human Services ("HHS"). One requirement of this CIA was to

provide training to its employees on the AKS and to provide guidance as to its potential implications, legal sanctions and examples of violations.

51. In addition, Medtronic's Code of Conduct provides:

> ***Customer & Patient Interactions***
>
> We have a responsibility to ensure that our interactions with customers and patients are ethical and beyond reproach. We will not attempt to influence a healthcare professional, patient, or customer through improper inducement. This means that we will not offer or provide an improper payment or other benefit to a customer as a reward for prior business or inducement for future business. We will adhere to our Global Business Conduct Standards (BCS) in order to build relationships based in integrity, trust, and honesty. Those of us who interact with customers must know, understand, and follow our BCS and any policies and procedures that apply to our work.
>
> "Customer" is defined as "any institution or individual, including any medical or healthcare professional or entity, in a position to purchase, lease, recommend, use or arrange for the purchase or lease of, or prescribe Medtronic products. For the purposes of the BCS, this also includes any person employed by a customer, close family member of, or an organization affiliated with the customer."
>
> ***Bribery***
>
> Our respect for our Stakeholders and our commitment to conduct our business with integrity means that we never offer or provide any form of bribe, illegal payment, or kickback. We do not offer or provide items of value in order to improperly induce or reward a customer for recommending, using, ordering, or purchasing a product or service. Likewise, we will not offer or pay for an unfair advantage in the marketplace, whether in areas of product approval, sales, research, permitting, hiring, or any other aspect of our business.

52. Boston Scientific is currently under, and in violation of a CIA it entered with the OIG of the U.S. Department of HHS in December 2009. Under the CIA, Boston Scientific is required to train all employees on the AKS and other laws they must abide by when selling and marketing Boston Scientific's products.

53. This CIA outlines detailed compliance requirements, as well as serious penalties for infractions of said requirements.

54. Boston Scientific's illegal activities, as described herein, are in blatant disregard to the CIA it entered. Boston Scientific, by providing free technical services to doctors and advising doctors that it is a billable service, flies in the face of the terms and conditions of the previous settlement with the federal government and shows utter disregard for the law.

55. Boston Scientific's Code of Conduct requires its employees to be fair and not misrepresent or omit information while doing their job. Its Code of Conduct reads:

> Be Fair to All Others
>
> Boston Scientific expects you to deal fairly with others. **This means you should not take advantage of anyone by misrepresenting or omitting important facts**, or through any other unfair business practice. You should never misrepresent or conceal your identity (emphasis added).

56. Boston Scientific took advantage of doctors by concealing the fact that the technical services it was providing to doctors was not a billable service and should not be billed by doctors.

57. St. Jude Medical's Code of Business Conduct states:

> Most countries in which the Company does business have laws and regulations that prohibit certain payments and donations to physicians and customers. One example is the United States Medicare/Medicaid Antifraud Statute. The Company's policy is to comply with all such laws and regulations. These are too complicated to be summarized in this code. Sales and Marketing employees and agents are expected to be familiar with the laws and regulations that govern them. In addition to complying with the pertinent laws and regulations, the Company will not:
>
> 1. Make any payment or donation to a physician or customer in exchange for the physician prescribing or the customer purchasing the Company's products.

58. As described herein, the free technical services St. Jude, and all other Defendants, are providing, amount to free payments to doctors done for doctors' loyal support and continued business.

59. Boston Scientific, Medtronic, St. Jude and Biotronik are all members of AdvaMed (the "Advanced Medical Technology Association").

60. Biotronik's website explicitly adopts the AdvaMed Code of Ethics and states, "[o]ur Code of Business Conduct is based on the AdvaMed Code of Ethics. BIOTRONIK is a strong and active supporter of the AdvaMed Code of Ethics."

61. AdvaMed represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities. Defendants, as members, have each certified compliance with the AdvaMed Code of Ethics (the "AdvaMed Code") and have announced their intention to comply with the AdvaMed Code.

62. Section 10 of the AdvaMed Code (effective July 1, 2009) states:

> **X. Provision of Coverage, Reimbursement and Health Economics Information**
>
> As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies.
>
> Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:
>
> • Identifying the clinical value of the Company's Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.
>
> • Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their

professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.

• Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company's Medical Technologies, including identifying coverage, codes and billing options that may apply to those Medical Technologies or the services and procedures in which they are used.

• Providing accurate and objective information about the economically efficient use of the Company's Medical Technologies, including where and how they can be used within the continuum of care.

• Providing information related to the Company's Medical Technologies regarding available reimbursement revenues and associated costs.

• Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional's decision to buy or use the Company's Medical Technologies.

• Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies.

• Facilitating patient access to the Company's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, at the request of a Health Care Professional to facilitate patient access to the Company's Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company's own Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional's independent clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. **For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement.** Further, a Company should not suggest

> mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

(emphasis added in bold)

63. At all times relevant to the Complaint, as more fully described below, all Defendants violated the AdvaMed Code, their respective codes of conduct, and the law by providing free technical services to monitor doctors' patients as an unlawful inducement to coax doctors into using their cardiac devices.

64. Each one knew that it was required to communicate with doctors that the technical component of a patient's follow-up was not a billable service for doctors. Instead of using transparent business practices, Defendants created a system of misperception which resulted in fraudulent billing by doctors. It was Defendants intent to cause doctors to bill for technical services and create a profitable situation for doctors in exchange for doctors' continued commitment to use their cardiac devices.

65. The AdvaMed Code also addresses the appropriateness and legality of research, educational grants and charitable donations.

> **XI. Research and Educational Grants and Charitable Donations**
>
> A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented.

66. At all times relevant to the Complaint, and as more fully described below, Defendants violated the AdvaMed Code, their respective codes of conduct, and the law by providing grant monies to fund cardiology fellowships and funds for sham research.

V. The "Technical" and "Professional" Components of a Cardiac Device Interrogation

67. The CIED industry is a leading source of revenue for medical device manufacturers with, approximately 3 million people in the United States with cardiac implantable devices, a majority of whom are Medicare/Medicaid beneficiaries. It is a multi-billion dollar industry.

68. The growth of CIED use in the United States is due to an aging population, and the necessary post-implantation follow-up, has resulted in a significant increase in Medicare and Medicaid spending over the last decade. *Greenspon, Arnold, M.D et al., Trends in Permanent Pacemaker Implantation in the United States from 1993 to 2009*, J. AM. COL. CARDIOLOGY, Vol. 60, No. 16, 2012

69. Patients with CIEDs require continued and repeated post-implant follow-up treatment to ensure that their device is working properly and that they remain in good cardiac health. This follow up is typically performed by the patient's cardiologist or a local hospital device clinic.

70. This CIED assessment is called an "interrogation." Generally, a device interrogation will assess whether the device is working properly. During an interrogation, the data in the device is accessed and evaluated. This data includes but is not limited to, battery life, the functionality of the lead wires, and record of any abnormal heart rhythms detected by the device or therapies issued. Gathering this information helps a doctor provide additional care to his / her patient and to determine whether adjustments to the device should be made.

71. Device interrogations have 2 distinct components: (1) technical; and (2) professional.

72. The technical component involves utilizing an interrogation unit to make sure the device is functioning correctly, assessing any device activity and making adjustments to the cardiac device with physician supervision. The technical component is done with a proprietary machine that has a wand which is held over the patient's heart. Each machine is different based upon the brand device implanted in the patient.

73. The professional component of a patient's interrogation includes doctor supervision, as well as discussion and analysis of the results with the patient.

74. Device interrogations are typically done by an employee of the device manufacturer alongside a patient's cardiologist; the doctor recommends adjustments, talks to the patient, reviews his or her results with them, and answers any questions that they may have.

75. On average, a patient requires two (2) to four (4) interrogations per year.

76. It is rare that a physician will conduct the technical component of the device interrogation due to certain complexities the device industry has created including operating the proprietary, highly complicated equipment needed to do the interrogation and more importantly, being unable to purchase the equipment for themselves. However, some doctors are trained to perform this task.

77. Instead, these services are provided by the Defendants gratis to doctors, such as Relators.

78. Defendants do not offer, require or ask the physician to purchase or lease these technical services.

79. Relators state that no contracts exist between Defendants and doctors or practices in relation to their providing free technical services.

80. Because Defendants' equipment is proprietary, no outside companies are able to contract these services to doctors; instead, doctors and patients are beholden to Defendants. This arrangement obligates physicians to rely on Defendants until the end of time.

81. Typically, the machine used to conduct the interrogation is brought to the doctor's office by a company representative.

82. On some occasions, however, Defendants will leave the machine on premises. This is usually done with larger volume cardiology practices that implant a considerable number of devices. Many times this includes teaching universities with electrophysiology divisions, large group practices or universities.

83. Yet, even when Defendants leave the equipment at the facility, they still send representatives to perform the technical component of the device interrogation for free. This is done even when physicians are trained and able to conduct the technical component of the interrogation themselves.

84. As discussed more fully below, as soon as a device representative visits a health care facility or office to conduct cardiac device interrogations, a cardiologist is not permitted to bill for the technical component of the device interrogation.

VI. Reimbursement for the "Technical" and "Professional" Components of a Cardiac Device Interrogation

85. After a patient's device is interrogated by one of the Defendants' representatives, doctors bill the patient's insurance for these services. Many cardiac patients are Medicare and Medicaid patients.

86. Like the actual interrogation itself, reimbursement for device interrogation is split into the same 2 basic billing categories: (1) a "professional component"; and (2) a "technical component." Billing for both services is referred to as "global" billing.

87. When a "global" billing code is used by a doctor for reimbursement, a five-digit number is used.

88. The five (5) global billing codes used are:

93279	[Single Lead] PROGRAMMING DEVICE EVALUATION (IN PERSON) WITH ITERATIVE ADJUSTMENT OF THE IMPLANTABLE DEVICE TO TEST THE FUNCTION OF THE DEVICE AND SELECT OPTIMAL PERMANENT PROGRAMMED VALUES WITH ANALYSIS, REVIEW AND REPORT BY A PHYSICIAN OR OTHER QUALIFIED HEALTH CARE PROFESSIONAL
93280	[Dual Lead] PROGRAMMING DEVICE EVALUATION (IN PERSON) WITH ITERATIVE ADJUSTMENT OF THE IMPLANTABLE DEVICE TO TEST THE FUNCTION OF THE DEVICE AND SELECT OPTIMAL PERMANENT PROGRAMMED VALUES WITH ANALYSIS, REVIEW AND REPORT BY A PHYSICIAN OR OTHER QUALIFIED HEALTH CARE PROFESSIONAL
93282-84	[ICD] PROGRAMMING DEVICE EVALUATION (IN PERSON) WITH ITERATIVE ADJUSTMENT OF THE IMPLANTABLE DEVICE TO TEST THE FUNCTION OF THE DEVICE AND SELECT OPTIMAL PERMANENT PROGRAMMED VALUES WITH ANALYSIS, REVIEW AND REPORT BY A PHYSICIAN OR OTHER QUALIFIED HEALTH CARE PROFESSIONAL
93288	INTERROGATION DEVICE EVALUATION (IN PERSON) WITH ANALYSIS, REVIEW AND REPORT BY A PHYSICIAN OR OTHER QUALIFIED HEALTH CARE PROFESSIONAL, INCLUDES CONNECTION, RECORDING AND DISCONNECTION PER PATIENT ENCOUNTER; SINGLE, DUAL, OR MULTIPLE LEAD PACEMAKER SYSTEM
93289	INTERROGATION DEVICE EVALUATION (IN PERSON) WITH ANALYSIS, REVIEW AND REPORT BY A PHYSICIAN OR OTHER QUALIFIED HEALTH CARE PROFESSIONAL, INCLUDES CONNECTION, RECORDING AND DISCONNECTION PER PATIENT ENCOUNTER; SINGLE, DUAL, OR MULTIPLE LEAD IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR SYSTEM, INCLUDING ANALYSIS OF HEART RHYTHM DERIVED DATA ELEMENTS.

89. If a doctor bills only for the "professional component" of the interrogation a 26-modifier must be used.

90. If reimbursement is submitted for the "technical component" only, a five number code with a hyphen and the letters "TC" must be used.

91. Under the law, ownership of the equipment is one of the determining factors for billing the technical service. The doctor's practice may bill for the technical service only if the he or she personally performs the technical service or employs the staff member who performs the technical service in the physician office. If a device industry representative is involved in performing the technical service, the doctor may only bill the professional service, i.e., physician analysis, review(s) and report(s).

VII. Defendants Created a System Lacking In Sufficient Compliance Controls with the Intent to Cause Doctors to Defraud the Government

92. Defendants knew that its actions (or many times inaction) would cause doctors to submit false or fraudulent claims to the government; this was done in exchange for doctors' loyalty and agreement to recommend use of their particular products.

93. Defendants have always known that the technical component of a cardiac device interrogation should not be billed by doctors unless they personally perform the technical service or employ the staff member who performs the technical service in the physician office.

94. Defendants have always known that if a device industry representative is involved in performing the technical service, the doctor may only bill the professional service.

95. Defendants' device representatives who render the technical services are not hired by or paid for by doctors. Defendants' technical services are never separately billed to doctors.

96. Relators, along with other doctors, have never been asked by any of the Defendants to purchase their technical service and have never been able to do so.

97. Relators, along with other doctors, have never been separately billed by Defendants for the technical services they have provided. Relator I has even asked whether he should provide payment for buying or leasing these services or whether the global billing should be "split-billed" and has been repeatedly told no.

98. Not once have Defendants' representatives instructed Relators or their colleagues that they cannot bill for their technical services; instead, they told Relator I that he could bill globally – for both the technical and professional components, and both Relators were encouraged to do so verbally and by completion of the global code on their respective billing sheets.

99. Relators state that unlike Defendants, other vendors regularly enter into contracts with doctors and either lease or sell them equipment, or split-bill services. Some of these types of contracts are for equipment and services related to nuclear cardiology testing, holter monitors, vascular testing, sleep studies and telemetry devices.

100. Upon information and belief, in the fall of 2013, St. Jude made an internal decision to no longer provide technical support in doctors' offices so as not to facilitate doctors' inappropriate global billing practices.

101. Upon information and belief, realizing that failing to provide technical services would detrimentally impact cardiac device sales, St. Jude instead issued a 10-page Physician Reimbursement Guide which became effective January 1, 2014.

102. St. Jude's Physician Reimbursement Guide confirms that doctors should not be billing for the technical component of a patient's cardiac device interrogation when a device representative is performing the service for free.

103. Relators state that St. Jude has never provided either of them with the Physician Reimbursement Guide nor did they direct them to a website or hotline where this information could be found.

104. Similarly, in 2012, Biotronik published a *Pacemaker, ICD and ICM Evaluation 2012 Reimbursement Overview* (the "Reimbursement Overview") to address billing practices.

105. Biotronik's Reimbursement Overview also makes clear that doctors are not to bill for technical services which are provided by their device representatives.

106. Relator's state that Biotronik never provided them with the Reimbursement Overview; instead, Relators had to conduct and independent investigation to locate this information.

107. Instead of being forthright with critical billing information for technical services they are personally providing, Defendants are playing a game of hide and seek with doctors when it comes to critical reimbursement information.

108. Defendants' "hide and seek" policy has caused and continues to cause doctors to submit false and fraudulent claims to the government for technical services. Defendants know this is happening and fail to properly address it because each are afraid of losing critical market share in a highly competitive marketplace.

109. Moreover, in a majority of instances, the Defendant technicians interpret the cardiac device interrogation results and make recommendations and actual changes to the cardiac devices, thereby tainting physician professional billing.

VIII. Each Defendant Encourages Doctors to Submit False Claims for Reimbursement for Technical Services

A. Medtronic

110. On September 24, 2014, a Senior Clinical Specialist CVG (Cardiovascular Group) of Medtronic, Inc. Cardiac Rhythm Disease Management performed an in-office pacemaker interrogation of patient in a New Jersey cardiology office.

111. Medtronic's clinical specialist performed all of the technical interrogation of this patient's pacemaker.

112. No physician, medical professional or ancillary staff was present during the interrogation.

113. At the conclusion of the interrogation, Medtronic's clinical specialist completed the billing sheet for Relator II, noting that a Dual Lead Programming was performed and showing the doctor how it should be billed.

114. Medtronic's clinical specialist marked CPT code 93280, a "global" code for billing a dual lead programming.

115. Medtronic's clinical specialist did not include a "26" modifier on the billing sheet nor instruct anyone in Relator II's office that a 26-modifier should be used when submitting the claim for reimbursement.

B. Boston Scientific

116. On October 23, 2013, a Boston Scientific representative-technician performed technical services at Relator I's office.

117. At 2:46 p.m., the representative-technician performed an interrogation and reprogram of an ICD with dual pacemaker leads on a Medicare recipient.

118. He utilized the proprietary Boston Scientific equipment to interrogate the Medicare patient's cardiac implantable device.

119. He performed all of the functions of interrogation and reprogramming of the computer and did not wait for Relator I to be present for the interrogation.

120. After the interrogation was complete, the representative-technician supplied a Boston Scientific Device Follow-up Report to Relator I.

121. He then completed the cardiology billing encounter form and personally circled billing code 93283 to demonstrate to Relator which billing code was appropriate to submit.

122. As is common practice, this representative-technician did not instruct Relator I to use a 26-modifier nor advise him that his technical services were not reimbursable.

123. Instead, he told Relator I that 93283 – the global billing code – was appropriate for the services rendered.

124. At no time did this representative-technician or Boston Scientific request or receive monies for the technical services rendered.

125. Relator I did not submit the false bill to the CMS after consulting with outside counsel as to whether it was legal.

126. Upon learning of the fraud, Relator I instructed his billing supervisor to submit claims for professional services only which includes the 26-modifier.

C. St. Jude

127. Over the years, St. Jude made representations to Relators that they do not participate in technical billing they perform.

128. Defendant St. Jude has represented to Relator I that they are aware it is not appropriate for their representative-technicians to assist doctors with the technical component and not bill the doctor for it.

129. Relator I was told by a St. Jude representative that St. Jude has incurred and continues to incur serious expense as a result of performing the technical component of the cardiac device interrogations gratis for doctors, for which it is not reimbursed.

D. Biotronik

130. On November 13, 2013, a Biotronik representative performed a device interrogation for one of Relator I's patients.

131. The Biotronik representative evaluated the patient and performed the entire technical aspect of the ICD interrogation without the direct or general supervision of Relator or his staff.

132. Under neither the direct nor general supervision of Relator I nor his clinical staff, the Biotronik's representative concluded that there were no programing changes required for Relator I's patient.

133. At no time did Relator I or his staff participate, oversee or monitor the technical aspect of the ICD interrogation.

134. The Biotronik representative wrote down eight lines of documented information pertaining to the evaluation and gave them to Relator I.

135. The Biotronik representative informed Relator I that no programing changes were required for this patient, and provided Relator I with a print version of the device interrogation.

136. The Biotronik representative then advised Relator I that he could bill for the global service. She assisted Relator I by designating the global CPT billing code by marking it off on Relator I's billing form.

137. Relator I asked the Biotronik representative if payment to her for the technical component of the device interrogation was necessary; she said no.

138. This discussion was witnessed by one of Relator I's assistants.

139. At no time did the Biotronik representative inform Relator I that the technical component of the interrogation should not be billed by him.

140. The conduct, as described above, is indicative of that of which is happening on a continuous basis throughout the country. Relators I and II have repeatedly witnessed this conduct in the Commonwealth of Pennsylvania and the State of New Jersey. Relators I and II have spoken to colleagues and confirmed that Defendants have engaged in this scheme across the nation.

141. Defendants' widespread kickback scheme is done in an effort to impact device sales and to avoid any negative impact on market share should Defendants bill for the technical services rendered.

IX. Defendants Provide Fellowship Grants to High Volume Implanters for Loyal Use of Their Products

142. In and around 1998, CMS/Medicare ceased subsidizing subspecialty training programs in internal medicine and specific subspecialty training programs. Because CMS/Medicare did not make funding available for these subspecialty programs, hospitals, medical schools and clinical subspecialty practices controlled training of these subspecialty groups.

143. Without government funding, hospitals, medical schools and clinical subspecialty practices needed to find alternative sources of funding to continue subspecialty training programs.

144. Initially, the pharmaceutical industry and medical device manufacturers filled the void left after CMS/Medicare ceased subsidizing subspecialty training programs.

145. Within years, however, pharmaceutical companies largely withdrew funding of subspecialty programs.

146. Ultimately, it was necessary for cardiology subspecialty groups to procure funding for their training programs from the cardiac device companies.

147. Based upon information and belief, Defendants knowingly fund fellowship grants to subsidize cardiac fellows to do free work for the attending cardiologists, cardiology groups and/or hospitals.

148. Defendants target high-volume cardiologists, surgeons, cardiology groups and/or hospitals with rich financial incentives.

149. Relator I was told that, in exchange for use of their products, Defendants subsidize the salary and benefits for cardiac fellows at teaching programs at various universities and teaching hospitals.

150. The yearly cost of one cardiology fellowship is approximately $100,000.00.

151. Often times, the monies are earmarked as unrestricted grants given to a teaching university, which in turn gives the money to fund cardiac fellows, in order to conceal an intended kickback.

152. In fact, Relator I was told by another cardiologist that as soon as a contract of this type was signed with a New Jersey teaching institution, usage of that Defendant's particular cardiac devices increased by approximately 400%.

153. This same institution almost exclusively uses this Defendant's particular products

154. Not only does this type of funding result in an immediate increase in sales for the Defendants' respective products, it also creates an ongoing loyalty between doctors and Defendants, resulting in a long return on investment for Defendants.

155. The subsidization of these cardiac fellows amounts to kickbacks under the AKS and resulted in fraudulent claims submitted to federal health care programs.

156. Cardiology fellows are a huge perk to the practice because they assist cardiologists by working nights and weekends, and help with clinical work and general tasks that they would otherwise have to perform, such as patient consults.

157. Cardiologists from other cardiology groups who are not captive to a particular cardiac device manufacturer are not allowed to participate in the cardiology fellowship program and cannot get the benefit of the fellows' services.

158. Instead, these non-preferred cardiologists must hire with their own funds moonlighters, nurse practitioners and additional attending cardiologists at substantial cost.

159. Meanwhile, large cardiology groups who pledge allegiance to a certain device manufacturer do not have to cover fellowship costs because Defendants subsidize these costs.

160. According to Relator I, subsidization of cardiology fellows is a pervasive practice and was also done for well-known Pennsylvania teaching health programs.

161. A Biotronik representative told Relator I that he knows that a South Jersey cardiac group was not using Biotronik devices enough because it did not subsidize cardiology fellows or

offer any kickbacks to that particular group. He also stated that a particular healthcare system would not use its products unless it subsidized a cardiology fellow through its educational program.

162. Like St. Jude, Medtronic subsidizes cardiac electrophysiology fellowship training.

163. According to Relator I, Medtronic provided a New Jersey-based cardiologist with fellowship monies while he was actively practicing clinical cardiology as an attending.

164. Relator I states that Medtronic further compensated this cardiologist by paying for him to train simultaneously in another subspecialty.

165. Actions such as these lead to tainted referrals with an obligation of the training cardiologists and the training institution to use Medtronic devices.

166. Relator I learned this information on two separate occasions by a St. Jude representative and by a local clinical cardiologist.

167. Specifically, Relator I learned that this New Jersey cardiologist would not honor requests from other cardiologists to use a particular manufacturer's device and in turn, would use a Medtronic device because of his loyalty to Medtronic, disregarding referral doctors' orders.

168. Relator I also learned that this New Jersey cardiologist, many times, replaces cardiac device leads (the wires that connect the device to the heart) with Medtronic-brand leads. Hybrid devices are not always optimal; typically, a doctor should try to use the same manufacturer's leads and device instead of switching out parts.

169. Relator I was told that this New Jersey cardiologist creates hybrid devices to ensure his benefactor, Medtronic, receives revenue.

170. A St. Jude representative confirmed that, by creating hybrid devices, this particular cardiologist has created a quasi-fee splitting scenario to support Medtronic. Upon

information and belief, this type of quasi-fee splitting scenario happens nationally based on the amount of kickbacks paid to doctors.

171. As stated above, Medtronic has subsidized his electrophysiology fellowship and subsidized his career with large annual consulting stipends.

172. Further, this same St. Jude representative told Relator I that he believes that there has been overutilization of Medtronic devices in nursing home patients. This presents a serious health risk to elderly individuals because, under certain circumstances, implantation of a cardiac device is too high risk and increases the chance of death.

173. Relator I was also told that, at some point, a prominent Philadelphia hospital would not implant Biotronik devices because other companies were subsidizing their fellowship programs.

174. Relator I has learned from a former colleague that it was an ongoing practice at the particular institution referenced above within the past two (2) years.

175. Relator I has also learned of other South Jersey and Philadelphia institutions that will implant a majority of one Defendant's device due to financial arrangements with that particular company and financing of cardiac fellows.

176. Relators state that if only one device manufacturer supports a cardiology fellowship, there is a mutual expectation among the partners of the cardiology practice that doctors would almost exclusively use that manufacturer's products.

X. Defendants Provide Other Kickbacks Under the Guise of Consultant Fees and Research Stipends

177. Defendants employ high volume implanters as consultants who bring in tens of millions of dollars in revenue.

178. These physicians implant a high number of devices for a particular company per year.

179. Defendants pay these so-called consultants high volume large sums of money in the form of consultation payments.

180. Defendants make these payments to induce future referrals and implantation of their devices.

181. Upon information and belief, to receive the exorbitant consulting fees, the implanting physician needs to justify their high volume yearly and therefore have a bias to insert in devices in marginal patients.

182. Defendants induce these doctors to use only their CIEDs with handsome "consulting fees."

183. Given the inducement, any patient who goes to a particular physician for a device is a tainted referral because he/she may not be getting the appropriate device tailored to their clinical problems or gives the temptation to over utilize the devices. While CIEDs have similar attributes, each also have certain qualities that should be considered based on an individual patient's needs.

184. Instead the patient receives a device manufactured by the company which pays a handsome "consulting fee" to the physician.

185. Relators were told that an attending cardiologist in New Jersey employed and salaried by a prominent New Jersey hospital, is paid directly a consultant salary by Medtronic and also had a fellowship funded by Medtronic to train in electrophysiology.

186. This group, in turn, uses Medtronic devices almost exclusively.

187. Relators learned through a St. Jude's representative that this New Jersey cardiologist generates enormous revenue.

188. This doctor, in turn, is rewarded for his loyalty to Medtronic products with "consultant" fees.

189. A St. Jude representative told Relator I that this New Jersey cardiologist could not implant new and technologically superior device because it would conflict with his Medtronic arrangement.

190. As a result of the Medtronic incentive and kickback scheme, this New Jersey cardiologist denies patients medical benefits because of the financial inducement by Medtronic.

191. Consultant fees in the form of a *quid pro quo* – here, for exclusive loyalty and use of a Defendant's cardiac products, is a kickback and prohibited by the AKS.

192. Similarly, Defendants subsidize meaningless "Clinical Research" which, according to Relators, have no medical or academic purpose.

193. Relators state that Defendants provide clinical research stipends to large or high volume cardiologists and cardiology groups.

194. According to Relators, these clinical research projects are purposefully insignificant and rarely result in the publication of any peer review journal articles.

195. Defendants generally offer research projects to cardiology groups in exchange for research stipends. Some of this research is bona fide clinical work based upon evidence-based medicine. It is done for the betterment of patients and science.

196. According to Relators, sometimes Defendants offer what they would consider "sham research" projects as a technique to funnel monies to doctors in exchange for use of their cardiac products.

197. Defendants subsidize meaningless research projects at economically profitable cardiology groups as an economic inducement in exchange for use of their heart devices.

198. Many cardiology groups will not consider using a particular manufacturer's device unless they are paid research grant dollars.

199. Defendants generally only give clinical research stipends to large or high volume cardiologists and cardiology groups which implant a significant amount of devices.

200. In addition, a St. Jude representative and supervisor has told Relator I that a large-volume, private practice cardiology group in New Jersey, would only use St. Jude devices if St. Jude somehow funded the group. "Funding" to the cardiology group was made in the form of research grants and lavish meals.

201. By providing remuneration to doctors in the form of consultant fees and research stipends, Defendants intended to induce those doctors to use their products. It was reasonably foreseeable that some of those medical devices would be for federal health care program beneficiaries and that claims for those cardiac devices would be submitted to federal health care programs. Thousands of such claims were, in fact, submitted and reimbursed by federal health care programs.

XI. Fraud on the Federal Health Care Programs Though Use of Pacemaker Mills

202. To further this fraud to benefit the physicians who are the predominant source of revenue, the cardiac device manufacturers support "pacemaker mills" to provide post-implant follow-up, the technical consulting services for a greater number of pacemakers, and defibrillators.

203. These "pacemaker mills" are supervised by cardiologists and electrophysiologists.

204. Even if there is a nurse or other personnel from the cardiologist practice, or even if the cardiologist is in the room, once the technician is in the room, they expedite the interrogation of the patient's device and the performance of the technical component.

205. This expediting characteristic can permit a pacemaker clinic to interrogate and perform technical services on up to four to five patients per hour or more.

206. Based on representation from St. Jude officials, and also from personal communications with both an electro-physiologist and a cardiologist affiliated with a prominent New Jersey health system, there are pacemaker clinics throughout the United States where patients are pushed through at a high volume with device manufacturer's representatives present during these episodes.

207. The physicians in these pacemaker mills are billing professional and technical components.

208. Relator I knows of at least two (2) pacemaker mills located in southern New Jersey.

209. One St. Jude representative informed Relator I about a cardiology practice where patients are having device representatives of different companies do the entire technical portion of device interrogations and billing of these tests globally for a multitude of these tests on a single day.

210. These pacemaker mills greatly contribute to the kickback scheme and submission of false claims because under these circumstances, physicians are submitting large reimbursement requests to government health care programs for technical services that they never perform.

211. Relator II has witnessed the same CMS global billing violation, when the Defendants' technicians perform the technical component of the interrogations at his own group's pacemaker clinic.

XII. Medtronic Causing the Submission of False Claims Through the Use of Enhanced CMS Billing

212. Within the past five (5) years, Medtronic developed a unique cardiac device with impendence monitoring, a special tool which allowed the device to monitor fluid balance and congestive heart failure in patients.

213. Several years ago, when impendence monitoring was first introduced, Relator I attended a dinner meeting with several cardiologists at Fogo de Cho in Philadelphia, hosted by Medtronic.

214. During this dinner meeting, Medtronic's sales representative gave a PowerPoint presentation outlining to cardiologists the advantages this device had over other cardiac devices.

215. During his presentation, the Medtronic representative also showed the doctors how they could obtain additional compensation and enhance their billings if they used this Medtronic cardiac device exclusively.

216. Because this cardiac device had an extra feature, one could use a special billing code to obtain additional compensation. Doctors were told that using this device would generate a new stream of revenue for their practices.

217. This is just one more example of how Medtronic, like the other Defendants, encourage doctors to overbill in exchange for continued commitment and use of their products.

COUNT ONE
Violations of Federal False Claims Act
31 U.S.C. § 3729(a)(1) (2006) and, as amended, 31 U.S.C. § 3729(a)(1)(A)

218. Plaintiff incorporates by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

219. This Count is brought by Relator I and Relator II the name of the United States under the qui tam provisions of 31 U.S.C. §3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

220. By virtue of the above-described acts, and in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), Defendants knowingly caused to be presented false or fraudulent claims for payment or approval of technical services rendered on cardiac device patients, in addition to other cardiac care, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States in violation of 31 U.S.C. § 3729(a)(1) (2006) and, as amended, 31 U.S.C. § 3729(a)(1)(A).

221. Plaintiff United States, unaware of the falsity of the claims and/or statements caused to be made by Defendants and in reliance on the accuracy thereof, paid the global fee for cardiac device interrogation that would otherwise not have been allowed by the government payors.

222. The amounts of the false or fraudulent claims caused by the Defendants to be submitted to the United States were material. By reason of Defendants wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim caused to be submitted by Defendants.

223. Relators believe and aver that they are each an original source of the facts and information on which this action is based.

COUNT TWO
Violations of False Claims Act
31 U.S.C. § 3729(a)(2) (2006), and as amended, 31 U.S.C. § 3729(a)(1)(B)

224. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

225. This Count is brought by Relator I and Relator II in the name of the United States under the qui tam provisions of 31 U.S.C. § 3730 for Defendant's violation of 31 U.S.C. § 3729(a)(2) (2006), and as amended, 31 U.S.C. § 3729(a)(1)(B).

226. By virtue of the above-described acts, and in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), Defendants knowingly caused to be made or used false records or statements to get false or fraudulent claims for payment or approval by the United States, and continues to make, use or cause false records and statements to be made or used to get false or fraudulent claims for payment or approval of technical services rendered on cardiac device patients, in addition to other cardiac care, paid or approved by the United States.

227. Plaintiff United States, unaware of the falsity of the records and/or statements caused to be made and used by Defendants, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for the global fee for cardiac device interrogations that would otherwise not have been allowed by the government payors and would not have been paid or approved in any part if the truth were known.

228. The amounts of the false or fraudulent claims caused by the Defendants to be submitted to the United States were material. By reason of Defendants' wrongful conduct, the United States has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus a civil

penalty of $5,500 to $11,000 for each such false statement caused to be made or used by Defendants.

229. Relators believe and aver that they are each an original source of the facts and information on which this action is based.

COUNT THREE
Violations of the Stark Law
42 U.S.C. § 1395nn *et seq.*

230. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

231. This Count is brought by Relator I and Relator II in the name of the United States for Defendant's violation of 42 U.S.C. § 1395nn *et seq.*, the "Stark" law.

232. The Stark law prohibits the referral of Medicare and Medicaid beneficiaries by a physician to an entity for the provision of "designated health services" if the physician, or the physician's immediate family member, has a financial relationship with the entity, unless a statutory exception applies to that financial relationship.

233. The Stark law violation occurs when (i) a physician, who has a financial relationship with a medical device company, (ii) recommends inpatient and outpatient hospital services (which is considered a "designated health service" under Stark) that (iii) is paid for by a federally funded program (*e.g.*, Medicare).

234. The Stark law prohibits an entity (i.e. Defendants) from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.

235. Physician referral for cardiac device implantation is an inpatient service.

236. Similarly, physician referral for cardiac device interrogations qualify as outpatient hospital services.

237. Both are "designated health services" under the Stark law.

238. Both cardiac device implantations and cardiac device interrogations are paid for by federally funded health care programs.

239. Defendants, through paid consulting agreements with doctors, paid stipends for sham research, and paid cardiology fellowships, violated the Stark law. Defendants paid these physicians exorbitant fees which far surpassed fair market value for those services rendered, in exchange for the recommendation and use of their respective cardiac devices.

240. The financial arrangements with physicians set forth in Relators' Complaint, do not fall within any of the Stark law exceptions.

241. Defendants are strictly liable for violating the Stark law. By reason of Defendants' violations of the Stark law, the United States suffered substantial losses in an amount to be proved at trial, and is therefore entitled to multiple damages and civil penalties, to be determined at trial.

COUNT FOUR
Violations of the California False Claims Act
Ca. Government Code §12650 *et seq.*

242. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

243. This Count is brought by Relator I and Relator II in the name of the State of California under the qui tam provisions of the California False Claims Act, California Government Code §12651(a) pursuant to which treble damages and civil penalties are sought.

244. Defendants at all times relevant to this action each sold and promoted their respective CIEDs, and offered free technical services for their cardiac devices in the State of California.

245. Cal. Gov't Code §12651(a) provides liability for the costs of a civil action, a civil penalty of up to $10,000 and treble damages for all damages sustained by the state for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or any political subdivision;
(3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;
(4) is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

246. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of California, for the global fee for cardiac device interrogation, along with other cardiac treatment.

247. Specifically, Defendants have:

- caused thousands of false claims to be presented to the State of California,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

248. The amounts of the false or fraudulent claims to the State of California were material.

249. Plaintiff State of California, being unaware of the falsity of the claims caused to be submitted by Defendants and in reliance on the accuracy thereof paid and continues to improperly pay doctors for the global fee for cardiac device interrogations, along with other cardiac treatment.

COUNT FIVE
Colorado Medicaid False Claims Act
Colo. Rev. Stat. § 25.5-1-104 *et seq.*

250. Relators incorporate by reference and re-allege all above paragraphs as if fully set forth herein.

251. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

252. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

253. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

254. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

255. By reason of the Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

256. The State of Colorado is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SIX
Connecticut False Claims Act
Chapter 319v, Sec. 17b-301 *et seq.*

257. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

258. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

259. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut Government for payment or approval.

260. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Connecticut Government to approve and pay such false and fraudulent claims.

261. The Connecticut Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

262. By reason of the Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

263. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SEVEN
Violations of the Delaware False Claims Act
Del. Stat. Tit. VI. §1201

264. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

265. This Count is brought by Relator I and Relator II in the name of the State of Delaware under the *qui tam* provisions of the Delaware False Claims and Reporting Act, Delaware Statute Title VI, Section 1201.

266. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, CIEDs in the State of Delaware. Defendants have provided and continue to provide free technical services in relation to interrogations performed on their respective CIEDs.

267. The Delaware False Claims and Reporting Act, 6 Del Code Ann. §1201(a)(1) provides for liability for any person who: knowingly presents or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; . . . shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

268. The Delaware False Claims and Reporting Act, 6 Del. C. §1201(a)(2) provides for liability for any person who: knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; …shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

269. The Delaware False Claims and Reporting Act, 6 Del. C. §1201(a)(3), provides for liability for any person who: Conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; . . . shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

270. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Delaware, for the global fee for cardiac device interrogations of their respective CIEDs. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Delaware,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

The amounts of the false or fraudulent claims to the State of Delaware were material.

271. Plaintiff State of Delaware, being unaware of the falsity of the claims caused to be submitted by the Defendants, and in reliance on the accuracy thereof paid and continues to pay the global fee for cardiac device interrogations rendered on their respective CIEDs, as well as for implantation of CIEDs as a result of kickbacks.

COUNT EIGHT
District of Columbia False Claims Act
D.C. Code Ann. § 2-308.14 (a)(1)-(3), (7)

272. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

273. This is a claim for treble damages and penalties under the District of Columbia False Claims Act.

274. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

275. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

276. By virtue of the acts described above, Defendants conspired with each other and with others to defraud the District of Columbia by inducing the District of Columbia Government to pay or approve false or fraudulent claims.

277. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continue to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

278. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

279. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT NINE
Violations of the Florida False Claims Act
Fl. Stat. §§68.081-68.09

280. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

281. This Count is brought by Relator I and Relator II in the name of the State of Florida under the qui tam provisions of Florida False Claims Act, Fl. Stat. §§68.081-68.09.

282. Defendants at all times relevant to this action sold and marketed, and continues to sell and market, CIEDs in the State of Florida. Defendants have provided and continue to provide free technical services in relation to interrogations performed on their respective CIEDs in the State of Florida.

283. Fla. Stat § 68.082(2)(a)-(c) provide liability for any person who-

(a) Knowingly presents, or causes to be presented, to an officer or employee of an agency, a false or fraudulent claim for payment or approval; … Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;. . . is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

(b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;. . . is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

(c) Conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid; …is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

284. By virtue of the above-described acts, among others, Defendants caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Florida, for technical services rendered in connection with the follow-up interrogations rendered on their respective CIEDs.

285. Specifically, Defendants have:

- caused thousands of false claims to be presented to the State of Florida,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

286. The amounts of the false or fraudulent claims to the State of Florida were material.

287. Plaintiff State of Florida, being unaware of the falsity of the claims caused to be submitted by Defendants, and in reliance on the accuracy thereof paid and continues to pay the global fee for cardiac device interrogations, as well as for implantation of CIEDs as a result of kickbacks.

COUNT TEN
Violations of the Georgia State False Medicaid Claims Act,
O.C.G.A. § 49-4-168 *et seq.*

288. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

289. This is a *qui tam* action brought by brought by Relators I and Relators II and the State of Georgia to recover treble damages, civil penalties and the cost of this action, under the Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168 *et. seq.*

290. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, CIEDs in the State of Georgia. Defendants have provided and continue to provide free technical services in relation to interrogations performed on their respective CIEDs.

291. Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168.1(a), specifically provides in part:

> (a) Any person who:
>
> (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
>
> (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
>
> ...shall be liable to the State of Georgia for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

292. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

293. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Georgia,
- knowingly made, used or caused to be made or used false records to get false claims paid;

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

294. For example, the global fee for Defendants' respective cardiac device interrogations would not have been billed by doctors but for Defendants' fraudulent concealment of billing information and encouragements to doctors. As a result of this illegal scheme, these claims were improper in whole pursuant to the Georgia State False Medicaid Claims Act.

295. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

296. Each submission for reimbursement by a doctor for the global fee for cardiac device interrogation where the Defendants' technician performed some or all of the task, as opposed to the doctor, was submitted as a result of Defendants' illegal marketing practices and represents a false or fraudulent record or statement. Each claim for reimbursement for such services submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

297. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and doctors, and over many years.

298. The Georgia State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal conduct.

299. By reason of Defendants' acts, the Georgia State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

300. Georgia is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by each Defendant.

301. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

302. Relator I and Relator II are each private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to Georgia State False Medicaid Claims Act on behalf of themselves and the State of Georgia.

303. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT ELEVEN
Violations of the Hawaii False Claims Act
Haw. Rev. Stat. §661-21 *et seq.*

304. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Relators in the name of the State of Hawaii under the *qui tam* provisions of Hawaii False Claims Act, Haw. Rev. Stat. §661-21 *et seq.*

305. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, CIEDs in the State of Hawaii. Defendants have provided and continue to provide free technical services in relation to interrogations performed on their respective CIEDs.

306. The Hawaii False Claims Act, Haw. Rev. Stat § 661-21(a)(1)-(3) specifically provides that any person who:

> (1) Knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;...
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;...
>
> (3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;...
>
> * * *
>
> Shall be liable to the State for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages that the state sustains due to the act of that person.

307. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Hawaii.

308. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Hawaii,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

309. The amounts of the false or fraudulent claims to the State of Hawaii were material.

310. Plaintiff State of Hawaii, being unaware of the falsity of the claims caused to be submitted by Defendants, and in reliance on the accuracy thereof paid and continues to pay for

improper claims for reimbursement for the global fee for cardiac device interrogations, as well as for CIEDs implanted as a result of paid kickbacks.

COUNT TWELVE
Violations of the Illinois Whistleblower Reward and Protection Act
740 ILCS 175/1 *et seq.*

311. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein. This Count is brought by Relator I and Relator II in the name of the State of Illinois under the qui tam provisions of 740 ILCS 175/4 for Defendant's violation of 740 ILCS 175/3.

312. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, CIEDs in the State of Illinois. Defendants have provided and continue to provide free technical services in relation to interrogations performed on their respective CIEDs.

313. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/3 (a)(1)-(3), specifically provide that any person who:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;...

(2) Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;...

(3) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid;. . .

(a) is liable to State for civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

314. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause

to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Illinois.

315. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Illinois,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

316. The amounts of the false or fraudulent claims to the State of Illinois were material.

317. Plaintiff State of Illinois, being unaware of the falsity of the claims caused to be submitted by the Defendants, and in reliance on the accuracy thereof, paid and continues to pay for improper claims for reimbursement for the global fee for cardiac device interrogations, as well as CIEDs implanted as a result of paid kickbacks.

COUNT THIRTEEN
Violations of the Indiana False Claims and Whistleblower Act
IC 5-11-5.5 *et seq.*

318. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

319. This Count is brought by Relator I and Relator II in the name of the State of Indiana under the qui tam provisions of IC 5-11-5.5-4, for the Defendants' violations of IC 5-11-5.5-2.

320. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, CIEDs in the State of Illinois. Defendants have provided and continue to

provide free technical services in relation to interrogations performed on their respective CIEDs.

321. The Indiana False Claims and Whistleblower Act, Ind. Code § 5-11-5.5-2(b) (2008), specifically provides that by engaging in certain acts a person commits an unlawful act and shall be liable to the state for civil penalties of at least $5,000 and for up to three times the amount of damages that the state sustains because of the act of that person, including:

(1) Presents a false claim to the state for payment or approval; or

(2) making or using a false record or statement to obtain payment or approval of a false claim from the state; . . . or

i. conspiring with another person to perform an act described above; or

Causing or inducing another person to perform an act described [above].

322. Through the acts described above and otherwise, Defendants knowingly caused to be presented for payment and approval to the Indiana Medicaid program, possibly continues to cause to be presented, directly or indirectly, to officers, employees or agents of the State of Indiana, false and fraudulent claims in order to induce Medicaid reimbursement for the global fee for cardiac device interrogations, as well as for implantation of CIEDs generally.

323. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Indiana,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

324. As a result, Plaintiff Indiana reimbursed Medicare and Medicaid participating providers for ineligible claims, resulting in material financial losses to the State of Indiana.

325. Plaintiff State of Indiana, unaware of the falsity of the claims caused to be presented by Defendants, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims that would not have been paid or approved in any part if the truth were known.

326. By reason of Defendants' wrongful conduct, Indiana has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the State's false claims act in an amount to be determined at trial, plus civil penalties for each such false statement caused to be made by Defendants.

COUNT FOURTEEN
Iowa Medicaid False Claims Act
Iowa Code Ann. §685.1 *et seq.*

327. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

328. This is a claim for treble damages and penalties against all Defendants on behalf of the State of Iowa under the Iowa Medicaid False Claims Act, Iowa Code §685.1 *et seq*.

329. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for Defendants drugs to the State of Iowa.

330. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of Iowa to approve and pay such false and fraudulent claims.

331. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

332. By reason of the Defendants' unlawful acts, the State of Iowa has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

333. The State of Iowa is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants plus treble damages.

COUNT FIFTEEN
Violations of the Louisiana Medical Assistance Programs Integrity Law Louisiana Rev. Stat. §437 *et seq.*

334. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

335. This Count is brought by Relator I and Relator II in the name of the State of Louisiana under the *qui tam* provisions of the Louisiana Medical Assistance Programs Integrity Law, Louisiana Rev. Stat. §437 *et seq*.

336. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, CIEDs in the State of Illinois. Defendants have provided and continue to provide free technical services in relation to cardiac device interrogations performed on their respective CIEDs.

337. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46-438.3 provides:

(A) No person shall knowingly present or cause to be presented a false or fraudulent claim.

(B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;

(C) No person shall knowingly make, use, or cause to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.

338. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Louisiana.

339. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Louisiana,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

340. The amounts of the false or fraudulent claims to the State of Louisiana were material.

341. Plaintiff State of Louisiana, being unaware of the falsity of the claims caused to be submitted by Defendants, and in reliance on the accuracy thereof paid and continue to pay for claims that would not have been paid or approved in any part if the truth were known.

COUNT SIXTEEN
Maryland False Health Claims Act of 2010
Subtitle 6, False Claims Against State Health Plans and
State Health Programs, § 2-601 *et seq.*

342. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

343. This is a claim for treble damages and penalties under the Maryland False Health Claims Act of 2010, Subtitle 6.

344. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

345. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Maryland State Government to approve and pay such false and fraudulent claims.

346. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal business practices.

347. By reason of the Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

348. The State of Maryland is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SEVENTEEN
Violations of the Massachusetts False Claims Act
Massachusetts Gen. Laws c.12 §5(A)

349. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

350. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

351. This Count is brought by Relator I and Relator II in the name of the State of Massachusetts under the qui tam provisions of the Massachusetts False Claims Act, Massachusetts Gen. Laws c.12 §5(A).

352. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, CIEDs in the State of Illinois. Defendants have provided and continue to provide free technical services in relation to interrogations performed on their respective CIEDs.

353. The Massachusetts False Claims Act, Mass. Gen. Laws Ann. chap. 12, §5(B)(1)-(3), provides in part, that any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment; ...
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof; ...
>
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim; ...
>
> * * *
>
> shall liable to the commonwealth or political subdivision for a civil penalty of not less than $5,000 and not more than $10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

354. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Massachusetts.

355. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the Commonwealth of Massachusetts,
- knowingly made, used or caused to be made or used false records to get false claims paid,

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

356. The amounts of the false or fraudulent claims to the State of Massachusetts were material.

357. Plaintiff Commonwealth of Massachusetts, being unaware of the falsity of the claims caused to be submitted by the Defendants' conspiracies and in reliance on the accuracies thereof, paid for claims that would not have been paid or approved in any part if the truth were known.

COUNT EIGHTEEN
Violations of the Michigan Medicaid False Claims Act
M.C.L.A. 400.601 *et seq.*

358. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

359. This Count is brought by Relator I and Relator II in the name of the State of Michigan under the qui tam provisions of the Michigan False Claims Act, M.C.L.A. 4000.601 *et seq.*

360. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, their respective CIEDs in the State of Michigan.

361. Through the acts described above and otherwise, Defendants knowingly caused to be presented for payment and approval to the Michigan Medicaid and/or Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of Michigan, in order to induce

Medicaid and/or Medicare to pay the global fee for cardiac device interrogations, as well as for implantation of CIEDs generally.

362. Through the acts described above and otherwise, Defendants knowingly caused to be made or used, and continue to cause to be used or made, false and fraudulent records and/or statements, in order to get claims paid by Medicaid and/or Medicare that were not eligible for reimbursement.

363. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Michigan,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

364. The amounts of the false or fraudulent claims caused to be made to the State of Michigan were material.

365. Plaintiff State of Michigan, unaware of the falsity of the claims caused to be presented by Defendants, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims that would not have been paid or approved in any part if the truth were known.

366. By reason of Defendants' wrongful conduct, Michigan has suffered substantial financial losses in an amount to be proved at trial, and therefore is entitled to multiple damages

under the False Claims Act, to be determined at trial, plus the maximum allowable civil penalties for each such false statement and each false claim caused to made or used by each Defendant.

COUNT NINETEEN

Violations of Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421

367. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

368. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act brought by Relator I and Relator II on behalf of themselves and the State of Michigan.

369. By virtue of the acts described above, Defendants have violated the Michigan Medicaid False Claims Act.

370. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Michigan,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

371. For example, claims for reimbursement of the technical component of cardiac device interrogations would not have been presented but for the illegal encouragement and concealment by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Michigan's False Medicaid Claims Act.

372. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

373. Each payment for the global fee for cardiac device interrogations, as well as payments for CIEDs implanted as a result of company kickbacks, resulting from Defendants' illegal marketing practices represents a false or fraudulent record or statement. Each claim for reimbursement submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

374. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

375. The Michigan State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false and illegal conduct.

376. By reason of Defendants' acts, the Michigan State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

377. The State of Michigan is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by each Defendant.

378. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation

of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

379. Relator I and Relator II are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to Michigan's False Claims Act on behalf of themselves and the State of Michigan.

380. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

COUNT TWENTY
Minnesota False Claims Act
Minn. Stat. § 15C.01 *et seq.*

381. Relators incorporate by reference and re-allege all above paragraphs as if fully set forth herein.

382. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

383. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

384. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Minnesota State Government to approve and pay such false and fraudulent claims.

385. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

386. By reason of the Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

387. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-ONE
Violations of the Montana False Claims Act
2005 Mont. Code, CH. 465, HB 146, *et seq.*

388. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

389. This Count is brought by Relator I and Relator II in the name of the State of Montana under the qui tam provisions of the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, *et seq*.

390. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, their respective CIEDs in the State of Montana.

391. The Montana False Claims Act, Mont. Code Ann., § 17-8-403 provides for liability for *inter alia* any person who engages in any or all of the following conduct:

(a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;

(b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;

(c) conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity; . . .or

(h) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

392. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Montana.

393. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Montana,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

394. The amounts of the false or fraudulent claims Defendants caused to be made to the State of Montana were material.

395. Plaintiff State of Montana, being unaware of the falsity of the claims caused to be submitted by the Defendants and in reliance on the accuracy thereof paid and may continue to pay for improperly submitted claims for reimbursement for the global fee for cardiac device interrogations, as well as cardiac devices prescribed and implanted due to Defendants' illegal kickbacks.

396. At all times relevant to the Complaint, Defendants each acted with the requisite knowledge.

397. By virtue of the above-described acts, among others, Defendants knowingly engaged in conspiracies to defraud the Government of Montana by getting false claims allowed or paid by the government.

398. As a direct and proximate consequence of Defendants' conspiratorial conduct, the State of Montana has suffered significant, material financial damages in an amount to be proved at trial.

399. The State of Montana would not have suffered these devastating losses had the truth about Defendants' illegal practices and marketing conspiracies been known.

COUNT TWENTY-TWO
Violations of the Nevada False Claims Act
Nevada Rev. Stat. §357.010 *et seq.*

400. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

401. This Count is brought by Relator I and Relator II in the name of the State of Nevada under the qui tam provisions of Nevada Rev. Stat. §357.010 *et seq.*, "Submission of False Claims to State or Local Government."

402. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, their respective CIEDs in the State of Nevada.

403. Through the acts described above and otherwise, Defendants knowingly caused to be presented for payment and approval to the Nevada Medicaid program, possibly continues to cause to be presented, directly or indirectly, to officers, employees or agents of the State of Nevada, false and fraudulent claims in order to induce Medicaid reimbursement for the global fee for cardiac device interrogations of their respective CIEDs, as well as for cardiac devices prescribed and implanted as a result of kickbacks.

404. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Nevada,
- knowingly made, used or caused to be made or used false records to get false claims paid,

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

405. At all times relevant and material to this Complaint, Defendants knowingly caused false claims for payment or approval to be presented to officers and employees of the federal and state governments. As a result, the federal and state governments reimbursed Medicare and Medicaid, resulting in great financial loss to the Nevada government.

406. By virtue of the above-described acts, among others, Defendants each knowingly caused to be made or used and continue to cause to be made or used false or fraudulent statements to get claims allowed or paid by the State of Nevada.

407. The amounts of the false or fraudulent claims and statements caused to be made by Defendants to the State of Nevada were material.

408. Plaintiff State of Nevada, being unaware of the falsity of the claims and/or statements caused to be made or used by Defendants, and in reliance on the accuracy thereof paid and continues to pay for Defendants' technical services rendered to doctors, as well as for implantation of cardiac devices resulting from illegal kickbacks.

COUNT TWENTY-THREE
Violations of the New Hampshire False Claims Act
167:61-b *et. seq.*

409. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

410. This Count is brought by Relator I and Relator II in the name of the State of New Hampshire under the qui tam provisions of New Hampshire False Claims Act, 167:61-b *et. seq.*

411. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, their respective CIEDs in the State of New Hampshire.

412. Through the acts described above and otherwise, Defendants each knowingly caused to be presented for payment and approval to the New Hampshire Medicaid and Medicare programs, and continues to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of New Hampshire, to induce Medicaid and/or Medicare reimbursement for claims for the global fee for cardiac device interrogations, as well as the implantation of their respective medical devices which were done as a result of illegal kickbacks.

413. Through the acts described above and otherwise, Defendants knowingly caused to be made or used, and continue to cause to be made or used, false and fraudulent records and/or statements, in order to get claims allowed or paid by Medicaid and/or Medicare, that were not eligible for any such reimbursement.

414. Specifically, Defendant has:

- caused thousands of false claims to be presented to the State of New Hampshire,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

415. The amounts of the false or fraudulent claims to the State of New Hampshire were material.

416. Plaintiff State of New Hampshire, unaware of the falsity of the claims presented or caused to be presented by Defendants, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims for the global fee for cardiac device interrogations, as well as claims for Defendants' cardiac devices that were implanted as a result of illegal kickbacks.

417. By reason of Defendants' wrongful conduct, New Hampshire has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum penalties for each such false statement caused to be made or used by each Defendant and each such false claim caused to be submitted by each Defendant.

COUNT TWENTY-FOUR
Violations of the New Jersey False Claims Act,
N.J. STAT. § 2A:32C-1

418. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

419. This is a qui tam action brought by Relator I and Relator II in the State of New Jersey to recover treble damages, civil penalties and the cost of this action, under the New Jersey False Claims Act.

420. Defendants have and continue to engage in a continuous practice of causing to be submitted reimbursement requests for the global fee for cardiac device interrogations, as well as submissions for claims for implantation of their respective devices due to illegal kickbacks, with the result that it has: (a) knowingly presented and caused to be presented, to an officer and employee of the State of New Jersey, false and fraudulent claims for payment and approval; and (b) has knowingly made, used, and caused to be made and used, false records

and statements to get false and fraudulent claims paid and approved by the State of New Jersey.

421. The New Jersey False Claim Act prohibits any person from:

(1) Knowingly presenting, or causing to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;

(2) Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) Conspiring to defraud the state by getting a false or fraudulent claim allowed or paid.

422. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the New Jersey Medicaid program, claims which failed to disclose the material violations of the New Jersey False Claims Act.

423. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the New Jersey Medicaid program, claims which failed to disclose the material violations of the New Jersey False Claims Act.

424. Specifically, Defendants each have:

- Caused thousands of false claims to be presented to the State of New Jersey,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

425. For example, claims for reimbursement for the global fee for cardiac device interrogations would not have been presented but for the illegal encouragement and concealment by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of New Jersey False Claims Act.

426. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

427. Each submission for reimbursement by a doctor for the global fee for cardiac device interrogation that was performed by Defendants' technicians in whole or in part represents a false or fraudulent record or statement. Each claim for reimbursement for such services submitted to a State-funded health insurance program represents a false or fraudulent claim for payment. Also, any claims submitted for cardiac devices as a result of direct kickbacks paid by Defendants represent a false or fraudulent claim for payment.

428. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

429. The New Jersey State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

430. By reason of Defendants' acts, the New Jersey Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

431. New Jersey is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by each Defendant.

432. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

433. Relators I and Relators II each are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to the New Jersey False Claims Act on behalf of themselves and the State of New Jersey.

434. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

COUNT TWENTY-FIVE
Violations of the New Mexico Medicaid False Claims Act,
N.M. Stat ANN. §27-14-1 *et seq.*

435. Plaintiff incorporates by reference and re-alleges all of the foregoing paragraphs as if fully set forth herein.

436. This Count is brought by Relator I and Relator II in the name of the State of New Mexico under the qui tam provisions of the New Mexico Medicaid False Claims Act §27-14-1 *et seq.*

437. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, their respective CIEDs in the State of New Mexico.

438. Through the acts described above and otherwise, Defendants knowingly caused to be presented for payment and approval to the New Mexico Medicaid and/or Medicare programs, and continue to cause to be presented, false and fraudulent claims directly or indirectly, to officers, employees or agents of the State of New Mexico, in order to induce Medicaid and/or Medicare reimbursement for claims for the technical component of cardiac device interrogations that were not eligible for any such reimbursement, as well as the implantation of their particular cardiac devices.

439. Through the acts described above and otherwise, Defendants knowingly caused to be made or used, and continue to cause to be made or used, false and fraudulent records and/or statements, in order to get claims allowed or paid by Medicaid and Medicare that were not eligible for any such reimbursement.

440. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of New Mexico,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; ; and,
- failed to disclose the existence of the false claims it has caused to be presented.

441. The amounts of the false or fraudulent claims caused to be made to the State of New Mexico were material.

442. Plaintiff State of New Mexico, unaware of the falsity of the claims presented or caused to be presented by Defendants, and in reliance on the accuracy thereof, have paid and

approved, and continue to pay and approve, claims for that would not have been paid or approved in any part if the truth were known.

443. By reason of Defendants' wrongful conduct, New Mexico has suffered substantial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum civil penalty allowed under the state law for each such false claim caused to be submitted by each Defendant and each such false statement caused to be made or used by each Defendant.

COUNT TWENTY-SIX
Violations of the New Mexico Fraud Against Taxpayers Act
N.M. Stat. § 44-9-1 *et seq.*

444. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

445. This is a qui tam action brought by Relator I and Relator II on behalf of the State of New Mexico to recover treble damages, civil penalties and the cost of the civil action under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1.

446. N.M. Stat. Ann. § 44-9-3 (A) of the New Mexico Fraud Against Taxpayers Act provides that [a] person shall not:

> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee or this recipient of state funds a false or fraudulent claim for payment or approval;
>
> (2) knowingly make or use, or cause to be made or used, a false record or statement to obtain approval or payment on a false or fraudulent claim;
>
> (3) conspire to defraud the state by obtaining approval or payment on a false claim;
>
> ***
>
> (9) as a beneficiary of an inadvertent submission of a false claim and having subsequently discovered the falsity of the claim, fail to disclose the false claim to the state agency within a reasonable time after discovery.

447. Pursuant to N.M. Stat. Ann. § 44-9-3(B) of the New Mexico Fraud Against Taxpayers Act, proof of specific intent is not required for a violation of subsection A of Section 3.

448. Defendants at all times relevant to this action, sold and continues to sell their respective CIEDs in the State of New Mexico.

449. By virtue of the illegal conduct and the other misconduct alleged herein, including causing the submissions of non-reimbursable claims for the global fee for cardiac device interrogations, as well as for cardiac devices implanted as a result of illegal kickbacks, Defendants violated N.M. Stat. Ann. § 44-9-3(A) of the New Mexico Fraud Against Taxpayers Act with the requisite intent.

450. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of New Mexico,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

451. For example, claims for reimbursement of the global fee for cardiac device interrogations would not have been presented to the State of New Mexico but for the illegal encouragement and concealment by Defendants.

452. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

453. By reason of these improper payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged, in a substantial amount.

454. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

455. Relators are each private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to N.M. Stat. Ann. § 44-9-5 of the New Mexico Fraud Against Taxpayers Act on behalf of herself and the State of New Mexico.

456. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

COUNT TWENTY-SEVEN
Violations of the New York False Claims Act
State Finance Law, §187 *et seq.*

457. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

458. This Count is brought by Relator I and Relator II in the name of the State of New York under the qui tam provisions of the New York False Claims Act, N.Y. St. Fin. §187 *et seq.*

459. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, their respective CIEDs in the State of New York.

460. The New York False Claims Act, State Fin. Law § 189 specifically provides, in part, that a person commits an unlawful act if the person:

(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;

(c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid . . . .

461. Through the acts described above and otherwise, Defendants knowingly caused to be presented for payment and approval to the New York Medicaid and/or Medicare programs, and continue to cause to be presented, false and fraudulent claims, directly or indirectly, to officers, employees or agents of the State of New York, in order to induce Medicaid and or Medicare to reimburse Medicaid or Medicare participating providers the global fee for cardiac device interrogations, as well as the implantation of certain cardiac devices that were done, as a result of, illegal kickbacks.

462. Through the acts described above and otherwise, Defendants knowingly caused to be made or used, and continue to cause to be used or made, false and fraudulent records and/or statements, in order to get claims paid by Medicaid and/or Medicare that were not eligible for any such reimbursement.

463. Specifically, Defendants have:

- caused thousands of false claims to be presented to the State of New York,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,

- failed to disclose the existence of the false claims it has caused to be presented.

464. The amounts of the false or fraudulent claims to the State of New York were material.

465. Plaintiff State of New York, unaware of the falsity of the claims caused to be presented by Defendants, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims that would not have been paid or approved in any part if the truth were known.

466. By reason of Defendants' wrongful conduct, New York has suffered substantial financial losses in an amount to be proved at trial, and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus the maximum allowable civil penalties for each such false statement caused to made or used by each Defendant and each such false claim caused to be made by each Defendant.

COUNT TWENTY-EIGHT
North Carolina False Claims Act
N.C. Gen. Stat. §§1-605 *et seq.*

467. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

468. This is a claim for treble damages and penalties under the North Carolina False Claims Act.

469. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

470. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

471. By virtue of the acts described above, Defendants conspired with each other and with others to defraud North Carolina by inducing the North Carolina State Government to pay or approve false or frauduient claims.

472. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

473. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

474. The State of North Carolina is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-NINE
Violations of the Oklahoma Medicaid False Claims Act,
63 Okla. Stat. § 5053, et seq.

475. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

476. This is a qui tam action brought by brought by Relator I and Relator II and the State of Oklahoma to recover treble damages, civil penalties and the cost of this action, under the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et. seq*.

477. Defendants have engaged in a continuous practice of causing to be submitted reimbursement requests for the global fee for cardiac device interrogations, as well as submissions for claims for implantation of their respective devices due to illegal kickbacks, with the result that it has: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Oklahoma, false and fraudulent claims for payment and approval; and

(b) has knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Oklahoma.

478. The Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053.1 (B), specifically provides in part:

> (B) Any person who:
>
> (1) knowingly presenting or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state; and,
>
> (3) conspires to defraud the state by getting a false claim allowed or paid by the governmental entity; ...
>
> Is liable to the State of Oklahoma for a civil penalty of not less than $ 5,000.00 and not more than $10,000.00, ... plus three times the amount of damages which the state sustains because of the act of that person.

479. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Oklahoma Medicaid program, claims which failed to disclose the material violations of the Oklahoma Medicaid False Claims Act.

480. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Oklahoma,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

481. For example, claims for the global fee for cardiac device interrogations where Defendants' technicians conducted the cardiac device interrogation in whole or in part, were improper in whole pursuant to the State of Oklahoma State False Medicaid Claims Act.

482. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

483. Each submission for reimbursement for the technical component of cardiac device interrogations performed by Defendants submitted as a result of Defendant' illegal practices represents a false or fraudulent record or statement. Each claim for reimbursement submitted to a State-funded health insurance program for medical devices implanted as a result of Defendant's illegal kickbacks represents a false or fraudulent claim for payment.

484. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

485. The Oklahoma State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for illegal conduct.

486. By reason of Defendants' acts, the Oklahoma State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

487. Oklahoma is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

488. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

489. Relators are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to Oklahoma False Medicaid Claims Act on behalf of herself and the State of Oklahoma.

490. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

COUNT THIRTY
Violations of the Rhode Island False Claims Act,
R.I. Gen. Laws § 9-1.1-1, *et seq.*

491. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

492. This is a qui tam action brought by brought by Relator I and Relator II and the State of Rhode Island to recover treble damages, civil penalties and the cost of this action, under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et. seq*.

493. Defendants have engaged in a continuous practice of causing to be submitted reimbursement requests for the global fee for cardiac device interrogations, as well as submissions for claims for implantation of their respective devices due to illegal kickbacks, with the result that it has: (a) knowingly presented and caused to be presented, to an officer and employee of the State of Rhode Island, false and fraudulent claims for payment and approval;

and (b) has knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Rhode Island.

494. The Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-3(a), specifically provides in part:

> (a) Any person who:
>
> (1) Knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;
>
> (3) Conspires to defraud the state by getting a false or fraudulent claim allowed or paid; ... is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person. A person violating this subsection (a) shall also be liable to the state for the costs of a civil action brought to recover any such penalty or damages.

495. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Rhode Island Medicaid program, claims which failed to disclose the material violations of the Rhode Island False Claims Act.

496. Defendants knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Rhode Island Medicaid program, claims which failed to disclose the material violations of the Rhode Island False Claims Act.

497. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Rhode Island,
- knowingly made, used or caused to be made or used false records to get false claims paid,

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

498. For example, claims for reimbursement for the global fee for cardiac device interrogations were inappropriate and would not have been presented but for the Defendants' encouragement and concealment that this service, as provided by Defendants, and were improper under the State of Rhode Island False Claims Act.

499. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

500. Each submission for reimbursement for the global fee for cardiac device interrogations performed by Defendants submitted as a result of Defendant' illegal practices represents a false or fraudulent record or statement. Each claim for reimbursement submitted to a State-funded health insurance program for medical devices implanted as a result of Defendant's illegal kickbacks represents a false or fraudulent claim for payment.

501. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

502. The Rhode Island State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendant's improper conduct.

503. By reason of Defendants' acts, the Rhode Island State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

504. Rhode Island is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

505. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

506. Relators are private persons with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to the Rhode Island False Claims Act on behalf of themselves and the State of Rhode Island.

507. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

COUNT THIRTY-ONE
Violations of the Tennessee Medicaid False Claims Act
Tenn. Stat. §§75-1-181 *et seq.*

508. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

509. This Count is brought by Relator I and Relator II in the name of the State of Tennessee under the qui tam provisions of the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75-1-181 *et seq*.

510. Defendants, at all times relevant in this action, have engaged in a continuous practice of causing to be submitted reimbursement requests for the global fee for their

respective cardiac device interrogations, as well as submissions for claims for implantation of their respective devices due to illegal kickbacks, in the State of Tennessee.

511. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Tennessee.

512. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Tennessee.

513. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Tennessee,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

514. The amounts of the false or fraudulent claims to the State of Tennessee were material.

515. Plaintiff State of Tennessee, being unaware of the falsity of the claims and/or statements caused to be made by the Defendants, and in reliance on the accuracy thereof paid and may continue to pay for claims that would not have been submitted but for Defendant's improper conduct.

COUNT THIRTY-TWO
Violations of the Tennessee False Claims Act
Tenn. Code Ann. § 4-18-101 *et seq.*

516. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

517. This is a qui tam action brought by Relators on behalf of the State of Tennessee to recover treble damages, civil penalties and the cost of the civil action under the qui tam provisions of the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.*

518. Tenn. Code Ann. §4-18-103, titled "Liability for violations," provides:

> (a) Any person who commits any of the following acts shall be liable to the state or to the political subdivision for three (3) times the amount of damages which the state or the political subdivision sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and shall be liable to the state or political subdivision for a civil penalty of not less than two thousand five hundred dollars ($ 2,500) and not more than ten thousand dollars ($ 10,000) for each false claim:
>
> (1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
>
> (3) Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;
>
> ***
>
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision;

519. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Tennessee,
- knowingly made, used or caused to be made or used false records to get false claims paid,

- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

520. The State of Tennessee, by and through Tennessee-funded health plans, and unaware of Defendants' illegal practices, paid the claims submitted by health care providers and third party payors in connection therewith.

521. Had the State of Tennessee known that Defendants violated the federal and state laws cited herein, it would not have paid the claims submitted by health care providers in connection with Defendants' fraudulent and illegal practices.

522. As a result of Defendant's violations of Tenn. Code Ann. §§4-18-103, the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive on interest.

523. Relators are private persons each with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Tenn. Code Ann. §§4-18-103 on behalf of themselves and the State of Tennessee.

524. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

COUNT THIRTY-THREE
Violations of the Texas Medicaid Fraud Prevention Act
Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*

525. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

526. This Count is brought by Relator I and Relator II in the name of the State of Texas under the qui tam provisions of the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*

527. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, their respective CIEDs in the State of Texas.

528. Specifically, Defendants have caused thousands of false claims to be presented to the State of Texas and:

- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

529. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continue to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the State of Texas.

530. The amounts of the false or fraudulent claims to the State of Texas were material.

531. Plaintiff State of Texas, being unaware of the falsity of the claims and/or statements caused to be made by the Defendants, and in reliance on the accuracy thereof paid and may continue to pay for claims that would not have been submitted but for Defendant's improper conduct.

COUNT THIRTY-FOUR
Violations of the Virginia Fraud Against Taxpayers Act
Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq.*

532. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

533. This Count is brought by Relator I and Relator II in the name of the Commonwealth of Virginia under the qui tam provisions of the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, § 8.01-216.1 *et seq*.

534. Defendants at all times relevant to this action sold and marketed, and continue to sell and market, their respective CIEDs in the Commonwealth of Virginia.

535. By virtue of the above-described acts, among others, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval, and continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the Commonwealth of Virginia.

536. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the Commonwealth of Virginia,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

537. The amounts of the false or fraudulent claims to the Commonwealth of Virginia were material.

538. Plaintiff Commonwealth of Virginia, being unaware of the falsity of the claims caused to be submitted by the Defendants, and in reliance on the accuracy thereof paid and continues to pay for claims that would not have been submitted but for Defendant's improper conduct.

COUNT THIRTY-FIVE
Washington Medicaid Fraud False Claims Act
West's RCWA 43.131.0001 *et seq.*

539. Relators restate and incorporate each and every allegation above as if the same were fully set forth herein.

540. This is a claim for treble damages and penalties under the Washington Medicaid False Claims Act.

541. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

542. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Washington State Government to approve and pay such false and fraudulent claims.

543. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

544. By reason of the Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

545. The State of Washington is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT THIRTY-SIX
Violations of the Wisconsin False Claims for Medical Assistance Act
WIS. STAT. § 20.931, *et seq.*

546. Relators incorporate by reference and re-allege all of the foregoing paragraphs as if fully set forth herein.

547. This is a qui tam action brought by brought by Relator I and Relator II and the State of Wisconsin to recover treble damages, civil penalties and the cost of this action, under the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et. seq.*

548. Defendant have engaged in a continuous practice of causing to be submitted reimbursement requests for the global fee for their respective cardiac device interrogations, as well as submissions for claims for implantation of their respective devices due to illegal kickbacks, in the State of Wisconsin.

549. Defendants have (a) knowingly presented and caused to be presented, to an officer and employee of the State of Wisconsin, false and fraudulent claims for payment and approval; and (b) has knowingly made, used, and caused to be made and used, false records and statements to get false and fraudulent claims paid and approved by the State of Wisconsin.

550. The Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931(2), specifically provides in part:

> (2) Except as provided in sub. (3), any person who does any of the following is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than 5,000 nor more than 10,000 for each violation:
>
> (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.

(c) Conspires to defraud this state by obtaining allowance or payment of a false claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program.

551. Defendant knowingly and intentionally caused to be made false statements and misrepresentations of material facts on applications for payment under the Wisconsin Medicaid program, claims which failed to disclose the material violations of the Wisconsin False Claims for Medical Assistance Act.

552. Specifically, Defendants each have:

- caused thousands of false claims to be presented to the State of Wisconsin,
- knowingly made, used or caused to be made or used false records to get false claims paid,
- conspired to defraud the state by getting false and fraudulent claims allowed or paid; and,
- failed to disclose the existence of the false claims it has caused to be presented.

553. As a result of this illegal scheme, these claims were improper in whole pursuant to the State of Wisconsin State False Medicaid Claims Act.

554. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

555. Each submission for reimbursement by a doctor for the global fee for a cardiac device interrogation where the company representative performed any part of the task, as opposed to the doctor, was submitted as a result of Defendants' illegal marketing practices and represents a false or fraudulent record or statement.

556. Relators cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by thousands of separate entities, and over many years.

557. The Wisconsin State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent practices.

558. By reason of Defendants' acts, the Wisconsin State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

559. Wisconsin is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by each Defendant.

560. Defendants did not, within a reasonable period of time after first obtaining information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

561. Relators are private persons each with direct and independent knowledge of the allegations in this Complaint, who have brought this action pursuant to the Wisconsin False Claims for Medical Assistance Act on behalf of themselves and the State of Wisconsin.

562. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

COUNT THIRTY-SEVEN
New York City False Claims Act
New York City Administrative Code §7-801-§7-810

563. Relators incorporate by reference and re-allege all above paragraphs as if fully set forth herein.

564. This is a claim for treble damages and penalties against Defendants on behalf of the City of New York under the New York City False Claims Act, New York City Administrative Code §7-801-§7-810.

565. By virtue of the above-described acts, among others, Defendants knowingly and willfully caused the submission of false claims by doctors for technical services they rendered on their respective CIEDs, as well as for claims for reimbursement for medical devices implanted as a result of illegal kickbacks.

566. By virtue of the above-described acts, Defendants knowingly made or caused to be made false claims for drugs to the New York City Government.

567. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York City Government to approve and pay such false and fraudulent claims.

568. The New York City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices.

569. By reason of the Defendants' unlawful acts, the City of New York has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

WHEREFORE, Plaintiff demands judgment against defendants as follows:

a. That by reason of the aforementioned violations of the New York City False Claims Act provisions that this Court enter judgment in the City of New York's favor and against Defendants in an amount equal to not less than two times and not more than three times the amount of damages that the City of New York has sustained because of Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $15,000 for each violation of the New York City False Claims Act, New York City Administrative Code §7-801-§7-810;

b. That Relator, as Qui Tam Plaintiff, be awarded the maximum amount allowed pursuant New York City Administrative Code § 704(i) and/or any other applicable provision of law;

c. That Relator be awarded all costs and expenses of this action, including attorney's fees and court costs incurred in the prosecution of this suit; and

d. That Plaintiff City of New York and Relator have such other and further relief that this Court deems just and proper.

COUNT THIRTY-EIGHT
City of Chicago False Claims Act
Municipal Code of Chicago §1-22-010-§1-22-060

570. Relators incorporate by reference and re-allege all above paragraphs as if fully set forth herein.

571. This is a claim for treble damages and penalties against Defendants on behalf of the City of Chicago under the Chicago False Claims Act, Municipal Code of Chicago §1-22-010-§1-22-060.

572. By virtue of the above-described acts, among others, Defendants knowingly made or caused to be made or caused to be made false claims for the global fee for cardiac device interrogations, as well as for their respective cardiac devices themselves, to the City of Chicago.

573. By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the City of Chicago to approve and pay such false and fraudulent claims.

574. The Chicago City Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal business practices.

575. By reason of the Defendants' unlawful acts, the City of Chicago has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

JURY DEMAND

576. Plaintiff demands trial by jury on all claims.

PRAYER FOR RELIEF

WHEREFORE, Relators, on behalf of themselves, the United States of America and the Plaintiff States, demand and pray that judgment be entered as follows against the Defendants Boston Scientific, Medtronic, St. Jude and Biotronik, under the Federal FCA Counts and under supplemental FCA counts of the Plaintiff States as follows:

(a) In favor of the United States against Defendants for treble the amount of damages to Government Health Care Programs (Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service) from the illegal marketing, selling, prescribing, pricing and billing alleged herein, plus the maximum civil penalties of $11,000 (plus interest) for each false claim caused to be submitted, for each false record submitted or caused to be submitted and each false claim

caused to be submitted by Defendants Boston Scientific, Medtronic, St. Jude Medical and Biotronik's conspiracy to submit false claims;

(b) In favor of the United States against the Defendants Boston Scientific, Medtronic, St. Jude Medical and Biotronik for disgorgement of the profits earned by each as a result of their illegal scheme;

(c) In favor of Relator I and Relator II for the maximum amount allowed pursuant to 31 U.S.C. §3730(d) to include reasonable expenses, attorneys' fees and costs incurred by Relators;

(d) For all costs of the Federal FCA civil action;

(e) In favor of Relator I and Relator II and the United States for such other relief as this Court deems just and equitable;

(f) In favor of Relator I and Relator II and the named State Plaintiffs against Defendants Boston Scientific, Medtronic, St. Jude and Biotronik in an amount equal to three times the amount of damages that the named Plaintiff States have sustained as a result of the Defendants' actions, as well as the statutory maximum penalty against the Defendants for each violation of each State's FCA;

(g) In favor of Relator I and Relator II the maximum amount allowed as Relators' share pursuant to the Plaintiff State FCAs as follows: the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, et seq., the California False Claims Act, Cal. Gov. Code §12651(a), the Delaware False Claims and Reporting Act, Del. Stat. Tit. VI. §1201, et seq., the District of Columbia False Claims Act, D.C. Stat. §2 308.03 *et seq*., the Florida False Claims Act, Fl. Stat. §§68.081-68.09, *et seq*., the Hawaii False Claims Act, Haw. Rev. Stat. §661 21 *et seq*., the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §439, *et seq*.,

Massachusetts False Claims Act, Mass. Gen. Laws c.12 §5(A), *et seq.*, the Michigan Medicaid False Claims Act, M.C.L.A. 400.601 *et seq.*; Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421; the Montana False Claims Act, 2005 Mont. Code, CH. 465, HB 146, *et seq.*, the Nevada False Claims Act, Nevada Rev. Stat. §357.010 *et seq.*, the New Hampshire False Claims Act, 167:61-b *et seq.*, the New Mexico False Claims Act, N.M. Stat ANN. §27-14-1 *et seq.*; New Mexico Fraud Against Taxpayers Act , N.M. Stat. § 44-9-1 *et seq.*; the New York False Claims Act, State Finance Law, §187 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Stat. §§75 1 181 *et seq.*; the Tennessee False Claims Act Tenn. Code Ann. § 4-18-101 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tx. Human Resources Code, Ch. 36, §36.101 *et seq.*, Indiana False Claims and Whistleblower Act, IC 5-11-5.5 *et seq.*, Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 *et seq.*, and the Virginia Fraud Against Taxpayers Act, Va. Stat. Ch. 842, Article 19.1, §8.01 216.1 *et seq.*; New Jersey False Claims Act, N.J. STAT. § 2A:32C-1; Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et seq.*; Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et seq.*; and the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq.*; plus interest;

(h) In favor of Relator I and Relator II for all costs and expenses associated with the supplemental claims of the Plaintiff States, including attorneys' fees and costs;

(i) In favor of the Plaintiff States and Relator I and Relator II for all such other relief as the Court deems just and proper; and,

(j) In the event that the United States or Plaintiff States proceed with this action, Relator I and Relator II, be awarded an appropriate amount for disclosing evidence or information that the United States and/or the Plaintiff States did not possess when this action

was brought to the government. The appropriate amount is not greater than twenty-five percent (25%) of the proceeds of the action or settlement of a claim. The amount awarded to Relators also includes the results of government actions or settlement of claims resulting from the expansion of claims through the government's further investigation directly generated from or attributable to Relators' information; and

(k) Such other relief as this Court deems just and appropriate.

December 29, 2014

Respectfully Submitted,

/s/ Joseph L. Messa

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